

1602/132

## 510(k) Summary

Date Prepared: April 3, 2002

<b>Manufacturer</b>	The Ludlow Company LP Two Ludlow Park Drive Chicopee, MA 01022 Registration Number: 1219103
<b>Manufacturing Location</b>	Uni-Patch 1313 West Grant Blvd. Wabasha, MN 55891 Registration Number: 2183164
<b>Contact Person</b>	M. Beth Rice Regulatory Affairs Manager Phone: (413)-593-8266 Fax: (413) 593-7266
<b>Device Trade Name</b>	Uni-Patch Ultrasound Coupling Gel
<b>Common Name</b>	Ultrasound gel
<b>Classification Name</b>	Transmission medium for acoustical coupling
<b>Regulatory Reference</b>	MUI
<b>Predicate Device</b>	Aquasonic 100 Ultrasound Transmission Gel
<b>Description:</b>	Uni-Patch Ultrasound Coupling Gel is a viscous, clear blue, water-soluble gel. Typical packaging configuration for the Uni-Patch Ultrasound Coupling Gel is 250 ml plastic bottles and 5 liter plastic containers.
<b>Intended Use</b>	Uni-Patch Ultrasound Coupling Gel is intended for use as the coupling medium for Ultrasound procedures on external, intact skin

### Physical and Technical Comparison:

Uni-Patch Ultrasound Coupling Gel is similar in terms of intended use and technological characteristics to predicate devices reviewed as coupling gels used to couple ultrasound devices to skin. The device is similar with respect to indications for use and physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.

<b>Performance Summary</b>	FDA has not established special controls or performance standards for this device
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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY 15 2002**

Ms. M. Beth Rice  
Regulatory Affairs Manager  
The Ludlow Company, LP  
Two Ludlow Park Drive  
CHICOPEE MA 01022

Re: K021132  
Trade/Device Name: Uni-Patch Ultrasound Coupling Gel  
Regulation Number: 21 CFR 892.1570  
Regulation Name: Diagnostic ultrasonic transducer  
Regulatory Class: II  
Product Code: 90 MUI  
Dated: April 3, 2002  
Received: April 9, 2002

Dear Ms. Rice:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

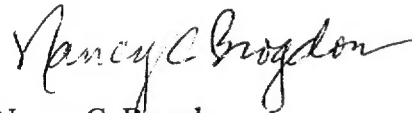
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021132

Device Name: Uni-Patch Ultrasound Coupling Gel

**Indications for Use:**

Uni-Patch Ultrasound Coupling Gel is intended to be used as an ultrasound coupling medium on external, intact skin for short duration.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use       

David A. Seymour

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K021132